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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/550,436	OBINATA ET AL.	
	Examiner	Art Unit	
	Anoop Singh	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-26 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-26 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' Preliminary Amendment, filed 9/23/05, has been entered. Claims 1-26 are pending; claims 4, 5, 9, 11, 15-17, 19-22 and 25 have been amended.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-6, drawn to a method to induce the differentiation of multipotent stem cells by a pharmacological agent wherein said agent promotes and or inhibits the differentiation of said cells in at least two directions.

Group II, claims 7-10 and 24-26, drawn to a method for evaluation of the ability of a pharmacological agent and to identify agent that promote or inhibit the differentiation of cells wherein the degree of differentiation of the multipotent stem cells caused by a proposed agent is compared with the degree of differentiation caused by bringing said cells into contact with cytokine that inhibits the differentiation of the cells.

Group III, claims 11-12, drawn to preparation for regenerative medicine which mainly comprising cells which have been induced with a pharmacological agent to promote or inhibit the differentiation of cells in at least two directions.

Group IV, claims 13-23, drawn to a set of cytokines to regulate the differentiation of cells of mammals, which comprises a combination of two or more cytokines as an effective ingredient, capable of determining three or more directions of differentiation of multipotent stem cells including bone marrow stromal cells, and is capable of regulating the degree of differentiation in each of cells whose differentiation direction has been determined.

The inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: In the instant case, claims are directed to a method to induce differentiation of multipotent stem cell by contacting cell with any agent during the growth of the cells wherein agent is capable of promoting and or inhibiting the differentiation of the cell in at least two directions. Okuyama (Exp Cell Res. 1995; 218(2):424-9) et al) teach stromal cell from bone marrow of temperature sensitive T-antigen transgenic mouse that could be induced to cell type of mesenchymal lineages (see page 424, material and method section). This further evident from another study that provided guidance with respect to bone marrow stromal cell lines (TBR cell lines) derived from temperature-sensitive T-antigen transgenic mouse exhibited myogenic, osteogenic, and adipogenic differentiation (Yanai et al In Vitro Cell Dev Biol Anim. 2001; 37(10):698-704). Specifically, Yanai et al show oncostatin M (OSM) treatment on such mesenchymal cell differentiation of marrow stromal cell lines resulted in differentiation of these cells into skeletal muscle, whereas differentiation of TBR10-1 cells into smooth muscle was inhibited by the treatment of OSM. It is noted that Okuyama contemplated studying differentiation potential of these cells at different developmental stage (see page 428, col. 2, last). It would be *prima facie* obvious for one of ordinary skill in the art to treat stromal bone marrow cell of different developmental stage with oncostatin M (OSM) to promote or inhibit differentiation in at least two directions. Therefore, the instant technical feature does not contribute over prior art.

In addition, the inventions are distinct fro each from other because of the following reasons: In the instant case the inventions of groups I-II patentably distinct, each from other because they are drawn to methods that use material compositions that have distinct structure and have other utility. For instance method of group I requires contacting an agent with stem cells of the invention,

while method of group II additionally requires to compare with degree of differentiation caused by contacting cells with a cytokine. Furthermore, the composition of group III is drawn to a cell that could be used in materially different process including ex vivo cell therapy, while cytokine claimed in group IV could be used in other biological assay or growing cells. Each of these involves distinct and different method steps and composition and therefore, searching for distinct method steps and composition will not be coextensive and will require separate and independent searches in the patent and non-patent literature.

Each invention is directed to distinct goal, which comprises the use of multipotent stem cells obtained from temperature sensitive SV-40-T antigen transgenic mice in order to achieve its respective and intended objective. Thus, it follows from the preceding analysis that the claimed inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the reasons set forth above.

MPEP 1893.03(d) states: If an examiner (1) determines that the claims lack unity of invention and (2) requires election of a single invention, when all of the claims drawn to the elected invention are allowable (i.e., meet the requirements of 35 U.S.C. 101, 102, 103 and 112), the nonelected invention(s) should be considered for rejoinder. Any nonelected product claim that requires all the limitations of an allowable product claim, and any nonelected process claim that requires all the limitations of an allowable process claim, should be rejoined. See MPEP § 821.04 and § 821.04(a). Any nonelected processes of making and/or using an allowable product should be considered for rejoinder following the practice set forth in MPEP § 821.04(b).

Election of species:

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they

are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

oncostatin M (OSM), bone morphogenetic protein-2 (BMP-2), bone morphogenetic protein-4 (BMP-4), growth differentiation factor 5 (GDF-5) and transforming growth factor

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

Claims 1, 7 and 13, and claims dependent therefrom correspond to all the species listed above.

The following claim(s) are generic: 1, 7 and 13.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: each disclosed species type do not share a common structure feature in common with respect to their efficacy and differentiation potential. Thus, requirement of unity of invention is not fulfilled.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

BMP-2 and BMP-4; BMP-2 and OSM; BMP-2 and TGF-.beta.2; BMP-2, BMP-4 and OSM; OSM-BMP-4; OSM and TGF-.beta.2; OSM and GDF-5; OSM, GDF-5 and BMP-4; OSM, GDF-5, TGF-.beta.2 and BMP-4; BMP-2, OSM, GDF-5 and BMP-4; and BMP-2, OSM, GDF-5, TGF-.beta.2 and BMP-4.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

Claim 13, and claims dependent therefrom correspond to all the species listed above.

The following claim(s) are generic: 13.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: each disclosed species type do not share a common structure feature in common with respect to their efficacy and differentiation potential.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anoop Singh whose telephone number is (571) 272-3306. The examiner can normally be reached on 9:00AM-5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272- 4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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